EXHIBIT B-6

Form Non-PPE
Quality System
Franchise Internal Failure Investigation Report

10.04.13 JOURNOT Vincent VJD

FM-0001222 / Rev 9
CO: 100053077

Identification of Issue – Problem Statement / Description

Failure Investigation for (Check the one that applies):
☒CAPA # 130022 ☐Internal Audit Observation Ref: ☒NCR # NCR12-10293, NCR12-10960, NCR13-00712, NCR13-01136 ☐PQI # ☐Other:

Describe the Issue under Investigation (Answer the questions below or reference the location of the information)	
What was found?	Repeat of non-conformances for particles found on a temporary positioning aid during the assembly process for TVT at the Neuchâtel Manufacturing plant. First NCR was opened for particles found in positioning aids original container. Following NCRs were opened for particles found on products during specific defect audits.
When found?	Incidents between November 22th, 2012 and February 8th, 2013
Where found?	EWHU clean room, Neuchâtel manufacturing plant.
Who found it?	Operators and Quality Technician
Other / References	N/A

The team for this failure investigation consists of (List Team Members):		
	☒ Quality Assurance	Sandra Chamouton (QA Technician), Margaret Bolton (QA Engineering Lead)
	☒ Operations	Angelique Lou (Team Leader EWHU)
	☒ Engineering	Vincent Journot (Manufacturing Engineer)
	☒ Other	Nicolas Couthion (Laboratory Analyst) Severine Timoner Fortin (Procurement)

Review of Quality Data (Check all that apply and record document numbers and supporting information)

Information / Data Reviewed	Document numbers and supporting Information
☐ Device History Record, Batch Record or Lot Record	
☐ Maintenance Records (such as PM, Calibration, Log Book)	
☒ Procedures / Specifications / Control Plans	FT0507 revG, FT0096 revG, TME0110 revA, FT0149 rev10, FT452 revA, FT0094 rev20, EPG034 rev31
☒ Technical Reports (such as Process Validation, Design Verification/Validation, Technical files)	Documentations for TVT products : MVP, PVA-IQ, PVA-OQ, PVA-PQ, PVA-NPD, TMV
☐ Process Monitoring Data	
☐ Environmental Data	
☒ Risk Tool (such as pFMEA)	PFMEA: GDS-PFMEA-100951 rev B, GDS-PFMEA-100177 rev B, GDS-PFMEA-100178 rev J, GDS-PFMEA-100932 rev B.
☐ Defect Sample Evaluation	
☒ Others (Specify): NCR	NCR12-10293, NCR12-10960, NCR13-00712, NCR13-01136

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Failure Investigation – Cause and Effect Analysis

Provide supporting information for each potential cause. Refer to PR-0000344 for guide questions / considerations for each category.

Steps	Potential Cause Category	Description If N/A is documented below, explanation is required.
FI-1	**Machine** (including equipment and machine design)	N/A, No equipment or machine involved. Therefore machine is not a potential cause.
FI-2	**Man** (including human error) Appendix I Not Applicable: ☒ Potential Cause not Man related. ☐ Associate no longer with company ☐ Due to time lapse, associate could not recall information. ☐ Interviewee could not be determined ☐ Other reason, see description for Man	N/A, Not related to Human error, as the operators have followed the process of assembly of the meshs with the temporary positioning aid as per the procedures listed in Review of Quality Data. Therefore Man is not a potential cause.
FI-3	**Material** (including raw materials, production materials, and finished product. Also including design)	Modification of supplier manufacturing process for this positioning aid was also reviewed as previously no NCR's had been opened for this defect. This potential cause cannot be confirmed as a potential root cause as we don't have material specification related to purchasing activities of this positioning aid. In addition of this conclusion and upon Review of Quality Data, no material specification exists for this temporary positioning aid. Therefore material is one of the root causes as no material specification for this positioning aid is in place.
FI4	**Method** (Process)	Investigation review shows there is no change in utilization of the positioning aid in Neuchâtel manufacturing process. Cleaning operation to reduce particles quantity on positioning aid was added only after the first NCR. Therefore cleaning operation cannot be confirmed as one of the root causes as it was not yet in place before the first NCR. A review of the change control process was performed to identify if a process was existing for the introduction of this type of manufacturing aid. The procedures did not provide guidance or instructions for the introduction or change of manufacturing aid, such as the temporary positioning aid. Therefore method is one of the root causes as manufacturing aids are not captured within the Neuchâtel change control process. Manufacturing aid is defined within this Failure Investigation as item which is temporarily in contact with the product; machines and environment are not included in this definition.
FI-5	**Environment** (including Mother Nature)	N/A, Assembly process of the sheaths/mesh with the temporary positioning aid was performed in the clean room environment. Particles were initially found inside original packaging of positioning aids therefore particles come from positioning aids. Therefore Environment is not a potential cause.
FI-6	**Management** (including Management systems)	N/A, not related to Management error. Therefore Management is not a potential cause.
FI-7	**Business Systems or Software**	N/A, no business systems and no software involved. Therefore Business Systems or Software is not a potential cause.
	Different analysis utilized and Attached	☐ *Yes, see attached* ☒ *N/A*

Conclusion *(Select the appropriate cause(s). Repeat selection if necessary)*
☐ Assignable Cause is:
☒ Root Cause is: no material specification for this positioning aid is in place
☒ Root Cause is: manufacturing aids are not captured within the Neuchâtel change control process
☐ None Determined (provide evidence documentation):

Final Bounding Rationale
☐ Not Applicable, based on the fact that product is not involved.
☒ Initial bounding rationale is consistent to the cause(s). Changes to bounding not required.
☐ Initial bounding rationale is not consistent to the cause(s). Changes to bounding are required (Document in NCR).

Form Guidance: Please ensure that the following items, where applicable, have been addressed.
Ensure that Appendix One was completed if necessary.
All un-used sections of this document or any objective evidence/attachments contain N/As where applicable.
All pages of this form, along with any objective evidence/ attachments paginated with "page X of Y"
All required signature sections contain the name, signature and date.
All cross-outs are initialed, dated and explained where necessary.

LIST ANY ATTACHMENTS	☒ N/A, no attachment required.		
PREPARED BY (PRINT)	JOURNOT VINCENT		
SIGNATURE		**DATE**	10.04.13

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Appendix 1 - Human Error Cause Analysis (Applicable for Potential Cause Category: FI-2 Man)		
Interviewer	**Date of Interview**	**Interviewee(s)**
Interview the person(s) responsible for creating the error. Refer to PR-0000344 for questions to be considered. After completion of the interview, document the applicable attributes leading to the error. After attributes are chosen below, the Human Error Categorization will be able to be chosen. This form is intended to be completed electronically.		

HUMAN ERROR CATEGORIZATION	
☐ Learning Gap	Lack of skill or knowledge required to do the task correctly; lack of understanding of importance of correct method and consequences of nonconformance. ☐ Employee was not trained and signed off on the applicable task or procedures. ☐ Employee did not understand the reason for the controls in place. ☐ First time the employee performed the task. ☐ Employee has not performed the task(s) previously free of error. ☐ Procedure/record is not clear and /or is not well understood to employee. ☐ Procedures/job-aids are required, but were not in the immediate area.
☐ Memory Gap	Remembered inaccurately or did not remember information, skill, or action at time it was required. N A ☐ Employee does not perform the task often. ☐ Procedure was performed on a different shift than the employee than the normally works. ☐ Employee has performed the task(s) previously free of error. ☐ Error occurred after a time gap in performing activity (e.g. out of office, holiday, etc)
☐ Omission Error	Missed step and unaware. ☐ Step(s) missed. SJO 10.04.13 ☐ Verification step(s) were missed. ☐ Several tasks were involved simultaneously. ☐ The environment or conditions were very busy. ☐ This error occurred on overtime.
☐ Application Error	Knew but applied incorrect action or information. ☐ Employee understood the reason for the controls in place. ☐ Verification completed incorrectly ☐ Procedures/Job-aids (tools, signs, etc.) were available and utilized; however employee applied the incorrect action/information to the task.
☐ Decision Error	Consciously chose action or behavior which resulted in undesired outcome. ☐ Procedures / job-aids were in the immediate area and utilized; however employee had to make a decision ☐ New situation for the employee ☐ Decision made in haste /with urgency ☐ Decision made with limited/incorrect information
☐ No Human Error, Procedure found to be inadequate/lacking **Documented in FIR as Method (Process) under Potential Cause**	☐ Procedure does not reflect current practices and/or all steps. ☐ Procedures is not clear to the employee ☐ Procedure has ambiguity/vagueness

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